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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HOLT, ANDRIAE M	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/620,404	NTAMBI ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-11* is/are pending in the application.

4a) Of the above claim(s) *6-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 28, 2008 has been entered.

Claims 6-11 are pending in the application. Claims 6, 7, 8, 10 and 11 have been amended.

Election/Restrictions

Applicant's election with traverse of Group II, claim 7, in the reply filed on May 14, 2009 is acknowledged. The traversal is on the ground(s) that the search and examination would not impose a serious burden on the examiner and that claim 8 is a linking claim to all the restriction groups. This is not found persuasive because as cited in the restriction requirement issued March 18, 2009, the inventions are related processes, however, each has a different design. Each invention uses a different agent to reduce stearoyl-CoA desaturase 1 (SCD1). The agents, polyunsaturated fatty acids, antisense oligonucleotide, agents that inhibit enzymatic activity of SCD1, are classified in different classes, have different structures and features which would require an extensive search of the prior art, as such the restriction is proper for the reasons previously cited. Claim 8 is not a linking claim of each of the restriction groups. Claims 10 and 11 are dependent on claim 8, thus linking the claims. Claim 8 independently is a

separate invention that has a different design from the inventions of groups I and II. The agent is any agent that reduces SCD1 activity by inhibiting enzymatic activity of SCD1. The number of agents that can be used in the invention of claim 8 are varied. The agents are classified in different classes, have different structures and features which would require an extensive search of the prior art, as such the restriction is proper for the reasons previously cited.

Applicant's election with traverse of the antisense oligonucleotide species, a 20 mer antisense oligonucleotide complementary to the 5' end of the SCD1 mRNA that extends 2 base pairs beyond the 5' start site of transcription in the reply filed on May 14, 2009 is acknowledged.

The restriction and election of species requirements are still deemed proper and are therefore made FINAL.

Claims 6 and 8-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 14, 2009.

Claims 6-11 are pending in the application. Claims 6 and 8-11 will be withdrawn to a nonelected invention and species. Claim 7 will presently be examined to the extent they read on the elected subject matter of record.

Information Disclosure Statement

The Information Disclosure Statement filed July 28, 2008 is acknowledged.

Status of Claims

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

The provisional double patenting rejection of claims 1, 8 and 9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 48 of copending Application No. 11/195561 **is maintained**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 48 of copending Application No. 11/195,561. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the instant claims are drawn to a method of increasing insulin sensitivity in a human or non-human subject by inhibiting the enzymatic activity of SCD1 through administering an SCD1 inhibitor. Claim 48 of application '561 is drawn to a method for treating diabetes and insulin resistance in an individual comprising the step of administering to that individual an inhibitor of an SCD1 protein expression or activity. Both applications are drawn to administering an inhibitor of SCD1 activity for the purpose of treating insulin resistance/increasing insulin sensitivity. Therefore the instant claims are obvious over claim 48 of '561.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crooke et al. (US 7,132,529) in view of Monia et al. (US 6,284,538).

Applicant's Invention

Applicant claims a method of increasing insulin sensitivity by administering an agent for reducing stearoyl-CoA desaturase 1 activity to increase insulin sensitivity and then measuring insulin sensitivity and observing an increase in insulin sensitivity following a reduction in SCD1 activity. Applicant further claims the agent is an antisense oligonucleotide for SCD1.

Determination of the scope of the content of the prior art
(MPEP 2141.01)

Crooke et al. teach a method of inhibiting the expression of human SCD comprising contacting the cells or tissues in vitro with an antisense oligonucleotide (claim 10). Crooke et al. further teach antisense oligonucleotides as capable of modulating the expression of SCD (col. 3, lines 24-39), which has been implicated in various diseases including diabetes (col. 2, lines 1-5). As a result of the antisense oligonucleotide of Crooke et al. inhibiting the expression of SCD, the antisense oligonucleotide inherently increases insulin sensitivity by reducing SCD protein level. Crooke et al. teach the antisense compounds of the present invention can be utilized for diagnostics, therapeutics, prophylaxis, and as research reagents and kits. For therapeutics, an animal, preferably a human, suspected of having a disease or disorder which can be treated by modulating the expression of stearoyl--CoA desaturase is treated by administering antisense compounds (col. 14, lines 44-56). Crooke et al. teach the antisense compounds of the invention are useful for research and diagnostics, because these compounds hybridize to nucleic acids encoding stearoyl-CoA desaturase, enabling sandwich and other assays to easily be constructed to exploit this fact (col. 14, lines 58-63). Crooke et al. teach kits using such detection means for detecting the level of stearoyl-CoA desaturase in a sample may also be prepared (col. 14, lined 67-col. 15, lines 1-2). Crooke et al. teach in example 5, col. 37, lines 35-67-col. 38, lines 1-33, the preparation of a 20-residue, phosphorothioate-linked chimeric oligonucleotides comprising 10-residue DNA core surrounded by 5-residue 2'-O-methoxyethylribosides "wings" (elected species). Crooke et al. teach in example 10

antisense modulation of stearoyl-CoA desaturase expression can be assayed in a variety of ways known in the art (col. 41, lines 51-52). Crooke et al. teach protein levels of stearoyl-CoA desaturase can be quantitated in a variety of ways well known in the art, such as immunoprecipitation, Western blot analysis (immunoblotting), ELISA or fluorescence-activated cell sorting (FACS) (col. 42, lines 3-6).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Crooke et al. do not teach the measuring of insulin sensitivity. It is for this reason Monia et al. is joined.

Monia et al. teach antisense oligonucleotides, which are targeted to a nucleic acid encoding PTEN, and which modulate the expression of PTEN (col. 3, lines 29-31). Monia et al. teach in example 25, col. 50, lines 7-29, the effects of antisense inhibition of PTEN (ISIS 116847) on Blood Glucose Levels of db/db Mice-insulin Tolerance Test. Monia et al. further teach the process by which the mice were treated and insulin tolerance tested (lines 10-19). Monia et al. teach that these studies indicate that the PTEN antisense oligonucleotide is capable of increasing sensitivity to insulin (decreasing insulin resistance) and that treatment does not cause hypoglycemia. Monia et al. further teach in claim 27 a method of increasing insulin sensitivity in a diabetic animal comprising administering to said diabetic animal an antisense oligonucleotide……wherein the expression of PTEN is inhibited and insulin sensitivity is increased (col. 72, lines 58-62).

Finding a prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of the Crooke et al. and Monia et al. and provide a method of administering an antisense oligonucleotide to reduce stearoyl-CoA desaturase 1 activity to increase insulin sensitivity and measure the insulin sensitivity and observe an increase in insulin sensitivity because Crooke et al. teach antisense oligonucleotide compounds are capable of inhibiting the expression of human SCD by contacting the cells or tissues with an antisense oligonucleotide and that SCD has been implicated in various diseases including diabetes. Crooke et al. also teach that antisense compounds of the invention are useful for research and diagnostics, because these compounds hybridize to nucleic acids encoding stearoyl-CoA desaturase, enabling sandwich and other assays to easily be constructed to exploit this fact. Crooke et al. teach kits using such detection means for detecting the level of stearoyl-CoA desaturase in a sample may also be prepared.

One skilled in the art at the time the invention was made would have been motivated to measure insulin sensitivity because Crooke et al. teach that antisense nucleotides that reduce stearoyl Co-A can be used as diagnostic tools. In addition, Monia et al. teach a method of administering an antisense oligonucleotide to increase insulin sensitivity in diabetic mice and a method of measuring insulin sensitivity after administering the antisense oligonucleotide. As Crooke et al. teach the antisense oligonucleotides can be used as a diagnostic tool, it would have been obvious to use the oligonucleotides as a diagnostic tool to measure insulin sensitivity base on the

reduction of SCD1 caused by the oligonucleotides using the method taught by Monia et al.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments filed July 28, 2008 have been fully considered but they are not persuasive. Applicant argues that the Examiner has failed to appreciate that Monia affected translation of a gene in the insulin signaling pathway to get increased insulin sensitivity and that it bears little relation to Applicant's interference with SCD1 activity. In response to Applicant's arguments, Crooke et al. teach the antisense oligonucleotides that modulate SCD1 activity can be used as a diagnostic tool to measure the antisense modulation of SCD1 and protein levels of SCD1. Thus, it would have been obvious to the skilled artisan to use the oligonucleotides as a diagnostic tool to measure insulin sensitivity base on the reduction of SCD1 caused by the oligonucleotides and that the method taught by Monia et al. could be used to measure that reduction as Crooke et al. teach any standard method can be used to measure antisense modulation and protein levels.

None of the claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/John Pak/
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